HFI-35

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

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Refer to: CFN 1124743

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4040

May 14, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Fred Schisler
2546 Marston Road
New Windsor, Maryland 21776

Dear Mr. Schisler:

An inspection of your operation located in New Windsor, Maryland, was conducted by a representative of the State of Maryland under contract to the Food and Drug Administration on May 3, 1997. The State inspector confirmed that a calf purchased and sold by you on or about January 21, 1997, for slaughter for human food, to [redacted] was in violation of Section 402(a)(2)(D) of the Federal Food, Drug, and Cosmetic Act (Act).

USDA/FSIS analysis of tissues collected from that animal disclosed the presence of 30.00 parts per million (ppm) and 48.00 ppm of the drug Sulfamethazine in the liver and muscle tissues, respectively. A tolerance of 0.10 ppm has been established for residues of Sulfamethazine in the edible tissues of cattle (Title 21, Code of Federal Regulations, Section 556.670). The presence of this drug in edible tissues from this animal causes the food to be adulterated. You should have received a letter dated February 17, 1997, from USDA concerning this matter.

You should take prompt action to correct the above violation and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

The violation listed above is not intended to be an all-inclusive list. It is your responsibility to assure that your operations are in compliance with the law. As a dealer of animals, you are frequently the individual who introduces or offers for introduction into interstate commerce, the adulterated animal. As such, you share the responsibility for violating the Act. To avoid future illegal tissue violations, you should take precautions such as:

1. implementing a system to identify the animals you purchase, with records to establish traceability to the source of the animal;

2. implementing a system to determine from the source of the animal if the animal has been medicated and with what drug(s); and

3. if the animal has been medicated, implementing a system to withhold the animal from slaughter for an appropriate period of time to deplete potentially hazardous residues of drugs from edible tissue. If you do not want to hold the medicated animal, then it should not be offered for human food, but should be clearly identified and sold as a medicated animal.

You should notify this office in writing within 15 working days of the steps you have taken to bring your firm into compliance with the law. Your response should include each step taken to correct the violation and prevent its recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your reply should be sent to the Food and Drug Administration, Richmond Resident Post, 10710 Midlothian Turnpike, Suite 424, Richmond, Virginia 23235, to the attention of Scott J. MacIntire, Compliance Officer. Mr. MacIntire may be reached at (804)379-1627.

Sincerely,

Peter M. Dubinsky
Acting Director, Baltimore District

cc: USDA/FSIS
Northeastern Region
Mellon Independence Center
701 Market St., 2-B South
Philadelphia, Pennsylvania 19106-1576

cc: Maryland Department of Agriculture
Animal Health
50 Harry S. Truman Parkway
Annapolis, Maryland 20742